JUN - 3 2012

510(k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

November 1, 2011, Updated May 31, 2012

Submitter's Information [21 CFR 807.92(a)(1)]

Regulatory Contact
Allan Alward
88 Ashford Avenue
Dobbs Ferry, NY 10522

Sponsor/Manufacturer
Mini Lap Technologies, Inc.
88 Ashford Avenue
Dobbs Ferry, NY 10522
Contact: Dr. S. Ravikumar
Tel: 914 591 8400

FDA Establishment Registration Number is 3007123990

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Names

- MINI LAP Bipolar Electrocautery Devices

Device Common, Usual or Classification Names

Laparoscopic Instruments, Graspers, Cannula, Trocar, Manual Surgical Instruments, Bipolar Instruments

Classification Panel

Classification of this device would fall under the responsibility of the General & Plastic Surgery panel.

Class

Class 2 device under the following product codes/regulations:

- KOG, 21 CFR 876.1500, Endoscope Accessories
- FBQ, 21 CFR 878.5090, Trocar
- GEI, 21 CFR 878.4400, Electrosurgical cutting and coagulation accessories

Predicate Device [21 CFR 807.92(a)(3)]
The following devices have been identified as predicate devices:

- Wolf Medical Instruments Bipolar Forceps – K023813
- MINI LAP Instruments – K070686

Description of the Device [21 CFR 807.92(a)(4)]
The MiniLap Bipolar Electrocautery devices are a family of disposable bipolar electrosurgical graspers that directly penetrate soft tissue to access certain areas of the human anatomy without the need for a traditional insertion conduit. These disposable instruments are used for electrosurgical cauterization during general laparoscopic procedures.

Fabricated from a stainless steel alloy, MiniLap Bipolar instruments consist of an integrated 2.4mm (+/- .1mm) insulated needle/cannula shaft that houses a retractable grasper instrument. The shaft can be introduced percutaneously to the surgical site, after which the working portion of the instrument can be deployed to approximate and cauterize soft tissue. Each BiPolar instrument has a male connection provided as an integral part of the instrument that may be utilized for the bipolar connection when attached to standard two plug bipolar cables and their generators. The bipolar connection is compatible with manufacturers of standard dual female bipolar plug cables.

The instruments come in multiple lengths from 150mm to 300mm.

Intended Use [21 CFR 807.92(a)(5)]
The MiniLap Technologies family of BiPolar instruments with bipolar cautery have applications in a variety of general, thoracic, gynecologic (except for use in female sterilization), urologic, laparoscopic and endoscopic procedures for manipulation and coagulation of tissue.

Technological Characteristics [21 CFR 807.92(a)(6)]
We believe the MINI LAP Bipolar Electrocautery Devices are substantially equivalent to the predicate devices. see chart

Technological Characteristics Comparison Chart

Characteristic	Mini Lap Technologies BiPolar Electrocautery Devices	Richard Wolf Medical Instruments Corp. Bipolar Forceps	Mini Lap Technologies MINI LAP Instruments
510(k)	K113597	K023813	K070686
Indications for Use	The MiniLap Technologies family of BiPolar instruments with bipolar cautery have applications in a variety of general, thoracic, gynecologic (except for use in female sterilization), urologic, laparoscopic and endoscopic procedures for manipulation and coagulation of tissue.	For use in open and laparoscopic surgery where grasping, coagulating, and transecting tissue is indicated.	Penetrate soft tissue to access certain areas of the human anatomy. The devices are used to grasp, hold and manipulate other soft internal tissues as well as items such as hernia mesh.
Needle diameter	2.4mm ± .1mm	3.5 mm, 5 mm	2.4 mm
Device length	150-300 mm	320 mm, 450 mm	150-300 mm
Material Composition	Medical Grade Stainless Steel 17-7 SS, 300 SS	Medical Grade Stainless Steel	Medical Grade Stainless Steel 470 SS, 300 SS
Sterilization	Sterile, single use	Non sterile, reusable	Sterile, single use
Power Source	Bipolar Electrosurgical Generator	Bipolar Electrosurgical Generator	N/A
Power Ranges	70 watts maximum, 20-35 watts normal operating range	50 watts maximum, 20-35 watts normal operating range	
Safety	Safety Interlock Insulated shaft and jaws Compliant to applicable IEC electrical safety standards	Safety Interlock is not applicable Insulated jaws Compliant to applicable IEC electrical safety standards	Safety Interlock
Rotation	175 degree shaft rotation, each direction		360 degree shaft rotation

Performance Data [21 CFR 807.92(b)(1)]
The subject device has been subjected to and passed a variety of mechanical and electrical tests and evaluations. Additionally, the device is composed of biocompatible materials with a history of usage in the medical device industry.

Conclusion [21 CFR 807.92(b)(3)]
We believe the changes are minimal and conclude that the subject device is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MiniLap Technologies
% Mr. Allan Alward
Vice President Research and Development
88 Ashford Ave.
Dobbs Ferry, NY 10522

JUN - 3 2012

Re: K113597
Trade/Device Name: Mini-Lap Bipolar Electrocautery Devices
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 15, 2012
Received: May 16, 2012

Dear Mr. Alward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic & Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113597

Device Name: Mini-Lap Bipolar Electrocautery Devices

Indications for Use:

The MiniLap Technologies family of BiPolar instruments with bipolar cautery have applications in a variety of general, thoracic, gynecologic (except for use in female sterilization), urologic, laparoscopic and endoscopic procedures for manipulation and coagulation of tissue.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113597